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In the Supreme Court of the United States

SANDOZ INC.,
PETITIONER

v.

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,
RESPONDENTS

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR HOSPIRA, INC., CELLTRION HEALTHCARE CO., LTD., AND CELLTRION, INC. AS *AMICI CURIAE* IN SUPPORT OF THE PETITION FOR CERTIORARI

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QUESTIONS PRESENTED

Under 42 U.S.C. § 262(*l*)8), whether a notice of commercial marketing must be delayed until after FDA approval and, regardless, whether courts may enforce the notice provision with an automatic, 180-day injunction.

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INTRODUCTION AND INTEREST OF *AMICI CURIAE*

This case involves a critical part of an important statute that the Court has not yet addressed—the Biologics Price Competition and Innovation Act ("BPCIA" or "Act"). The Act creates an expedited path for licensing drugs called biosimilars. Absent review, the Federal Circuit's fractured ruling threatens to cause an unwarranted six-month delay in the marketing of biosimilar medications. Such delay is unsupported by the BPCIA's text or any patent rights of branded biologic makers—who already enjoy 12 years of marketing exclusivity under the Act, independent of any patent protection. Further, delay imposes multibillion-dollar burdens on the nation's health care system and harms those who need low-cost medicine. Given the importance of the issue to consumers, taxpayers, and competition in a vital new pharmaceutical industry, review is needed now.

As their name suggests, biosimilars are biologic drugs similar to branded biologics already licensed by the Food and Drug Administration ("FDA"). The Act says an applicant for FDA approval of a biosimilar product shall notify the brand 180 days before the product is marketed. This "notice of commercial marketing" serves one purpose: It allows the patentee to "seek a preliminary injunction * * * with respect

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* Pursuant to Rule 37.2(a), *amici* provided timely notice of their intention to file this brief. All parties consented, and the letters have been lodged with the clerk. In accordance with Rule 37.6, no counsel for any party has authored this brief in whole or in part, and no person or entity other than the *amici* has made a monetary contribution to the brief's preparation or submission.

to any patent" not yet litigated by the parties—if any such patent exists.

The questions here are whether that notice must be delayed until *after* FDA approval and, regardless, whether courts may enforce the notice provision with an automatic 180-day injunction. In a splintered decision, the Federal Circuit held that notice must be delayed until FDA approves the biosimilar product—regardless of whether the product is otherwise ready for marketing. Further, the court enjoined Sandoz from launching its product until six months after FDA approval, even though Amgen never sought an injunction based on patent rights.

The majority misconstrued the statute as supporting this 180-day injunction, as shown by Judge Chen's powerful dissent and the narrow role of the marketing notice in the larger BPCIA scheme. "Just as Congress' choice of words is presumed to be deliberate, so too are its structural choices." *Univ. of Tex. Sw. Med. Ctr.* v. *Nassar*, 133 S. Ct. 2517, 2529 (2013). The majority below, however, rewrote the BPCIA to award the branded manufacturer (Amgen) an automatic 180-day injunction to the detriment of competition and patients. In so doing, the court distorted the structure of the BPCIA—which is designed to *expedite* patent litigation that might otherwise slow biosimilar competition. The court also ignored the plain instruction of *eBay Inc.* v. *MercExchange, L.L.C.*, 547 U.S. 388 (2006), which reaffirmed that injunctions should ordinarily issue only where supported by equity's traditional four-factor analysis. The Court should grant review and reverse.

Amici and the larger drug industry have a vital interest in this petition. Hospira, a wholly-owned

subsidiary of Pfizer Inc., develops biosimilars, among other pharmaceutical products. Hospira has teamed with Celltrion, Inc., a Korean company that independently develops and manufactures biosimilar antibodies and novel drugs, along with Celltrion Healthcare Co., Ltd., which markets and distributes drugs developed by Celltrion, Inc. in more than 120 countries. *Amici* seek to introduce in the United States Celltrion's biosimilar version of Janssen Biotech, Inc.'s multibillion-dollar drug Remicade® (infliximab) at an affordable cost to patients suffering from debilitating diseases, including rheumatoid arthritis. Janssen sued *amici* under the BPCIA for, among other things, allegedly violating the 180-day notice provision. See *Janssen Biotech, Inc.* v. *Celltrion Healthcare Co., Ltd.*, 1:15-cv-10 (D. Mass.).

Like Amgen, Janssen purports to sue to enforce the notice of commercial marketing provision itself. That is, according to Janssen, *amici* must delay their notice until FDA approval and, with it, their product launch by 180 days—even if no patent rights support injunctive relief. Similar cases are pending throughout the country, and many investment decisions of industry participants await resolution of the question presented. Review is urgently needed.[1]

STATEMENT

The BPCIA created an expedited path for licensing biosimilars of previously-approved biologic medications. Under subsection (k)—which addresses "Licensure of biological products as biosimilar or inter-

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[1] Hospira is litigating a similar dispute against Amgen in *Amgen Inc.* v. *Hospira, Inc.*, 1:15-cv-00839 (D. Del.).

changeable" (42 U.S.C. § 262(k))—the biosimilar applicant may rely on data submitted by a branded biologic drug manufacturer ("sponsor"). In return, the sponsor receives 12 years of marketing exclusivity regardless of whether any patents cover the biosimilar. *Id.* § 262(k)(7)(A).

The petition here focuses on a different portion of the Act, subsection (*l*), which addresses patent rights that could delay marketing. The Federal Circuit conflated these separate subsections by concluding that a paragraph within subsection (*l*) conferred an *additional* 180 days of marketing exclusivity—even though Congress did not say so.

A. Subsection (*l*) creates an optional process to resolve patent disputes.

In enacting the BPCIA, Congress contemplated that a sponsor may have many patents that could be asserted against a given biosimilar application. To resolve such patent rights efficiently, subsection (*l*) of the statute, entitled "Patents," outlines a step-by-step process to determine when litigation as to particular patents may be filed. *Id.* § 262(*l*). Although this detailed patent exchange process—sometimes called the "patent dance"—is not mandatory, Congress imposed consequences for non-participation.

Under the statutory process, neither the sponsor nor the applicant can sue until certain events unfold. At the outset, under paragraph (*l*)(2), the applicant may provide the sponsor with the biosimilar application and information describing the applicant's manufacturing process. *Id.* § 262(*l*)(2)(A). If the applicant does *not* do so (the approach taken by Sandoz), the sponsor—but not the applicant—may bring an immediate declaratory judgment action for patent in-

fringement on patents of its choosing. *Id.* § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii).

If the applicant *does* provide the information (the approach taken by Celltrion), no one may sue yet. Instead, the sponsor reciprocates by providing a list of patents under which it "believes a claim of patent infringement could reasonably be asserted." 42 U.S.C. § 262(*l*)(3)(A)(i). If the sponsor does not do so, or omits some patents, the sponsor may not sue for infringement of "a patent that should have been included." 35 U.S.C. § 271(e)(6)(C). By penalizing the sponsor for not disclosing relevant patents, the statute encourages disclosure—moving the process along.

If the sponsor provides its patent list, the applicant may provide both a "detailed statement" of its factual and legal contentions for each listed patent and the applicant's own list of patents that reasonably could be asserted. 42 U.S.C. § 262(*l*)(3)(B). Through this information exchange, the BPCIA encourages the parties to agree upon "which, if any, patents" will be the subject of an "action for patent infringement." *Id.* § 262(*l*)(4)(A).

The final list of patents, which may give rise to an "immediate" infringement lawsuit, is determined either by agreement or by following certain steps—thus beginning the first statutory phase of litigation. *Id.* § 262(l)(6)(A),(B); 35 U.S.C. § 271(e)(2)(C). For any patent appearing on the final patent list, if the sponsor sues within 30 days, it may seek the full complement of infringement remedies—including injunctive relief and damages for lost profits. 42 U.S.C. § 262(*l*)(6)(A),(B); 35 U.S.C. § 271(e)(4). But if the sponsor does not file an infringement lawsuit within this 30-day period—or if its suit is "dismissed" or is

"not prosecuted * * * in good faith"—"the sole and exclusive remedy" is a "reasonable royalty." 35 U.S.C. § 271(e)(6)(A), (B).

Congress designed these procedures to resolve patent disputes on key patents first, thus speeding competition. For example, Congress recognized that the threat of a lost-profits award against the applicant could deter it from launching its product. So Congress penalized a sponsor for delaying litigation by barring it from recovering lost profits.

Moreover, nothing in the statute prevents the sponsor from seeking a preliminary injunction on any litigated patents at any time after the lawsuit begins—even when FDA approval is years away. As with any injunction, the only restrictions are the requirements of Article III and satisfying the traditional four-factor test, which considers the strength of the sponsor's claims and the risk of irreparable harm.

B. The 180-day notice under subsection (*l*)(8)(A) relates solely to a potential second litigation phase.

All of this leaves a question of timing: When can the parties litigate any patents that appeared in an initial patent list but were omitted from the final patent list—i.e., "phase-two patents"? Subject to an exception described below, neither the sponsor nor the applicant may sue on these secondary, phase-two patents "prior to the date notice [of commercial marketing] is received under paragraph (8)(A)." 42 U.S.C. § 262(*l*)(9)(A).

The bar on litigating phase-two patents can be lifted in one of two ways. *First*, as discussed in paragraph (*l*)(9)(A), the applicant can provide a notice of commercial marketing. This notice is described in

paragraph (8)(A), which says "[t]he subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." *Id.* § 262(*l*)(8)(A). If provided, this notice creates a 180-day period during which either the sponsor or the applicant may seek declaratory relief. As explained in paragraph (8)(B), the sponsor may then "*seek* a preliminary injunction * * * with respect to any [phase-two] patent." *Id.* § 262(*l*)(8)(B) (emphasis added). The injunction, therefore, is not automatic.

Second, the statute lifts the bar on litigating phase-two patents if, before the biosimilar launch, the sponsor requests notice of marketing but the applicant refuses. That is, if the sponsor is concerned that the applicant is about to launch (because approval is imminent or exclusivity will soon expire), the sponsor could request that the notice be provided. And if the applicant refuses to provide notice, the sponsor may immediately file a declaratory judgment action and seek an injunction. This can happen, for example, when FDA announces public hearings as to the biosimilar application. In that instance, the "sponsor, but not the subsection (k) applicant," may file an immediate declaratory judgment action on any phase-two patents. *Id.* § 262(*l*)(9)(B) (emphasis added). By referring to a "declaratory judgment action," as opposed to an "action for patent infringement," Congress contemplated litigation *before* actual infringement—that is, before the applicant launches its product.

In short, the marketing notice serves a limited purpose: It allows the sponsor, after receiving the notice, to "seek" an injunction based on any phase-two

patents. *Id.* § 262(*l*)(8)(B). Indeed, the notice serves no statutory purpose if either: (1) there are no phase-two patents (a common scenario, as discussed below); or (2) the bar on litigating phase-two patents otherwise has been lifted (e.g., because the applicant refuses to provide notice). The notice is not a requirement for FDA approval. Nor does it guarantee the sponsor market exclusivity, much less an automatic 180-day injunction.

C. The majority below invokes the notice provision to enjoin Sandoz from marketing for 180 days after FDA approval, regardless of patent rights.

In this case, the biosimilar applicant (Sandoz) refused to produce its application and manufacturing information in a timely manner, arguing that the statute does not require such production. App. 8a. Amgen sued for injunctive relief to enforce the (*l*)(2) disclosure requirements and the paragraph (*l*)(8) notice provision, but the district court denied that request. Amgen appealed and sought an injunction pending appeal under the traditional four-factor test. The Federal Circuit granted the injunction (App. 19a) and, in a split decision, addressed three issues of statutory interpretation (the latter two are the subject of Sandoz's petition).

First, a majority held that paragraph (*l*)(2)(A)—which says the biosimilar applicant "shall provide" its application within the prescribed 20-day timeframe—is not mandatory. The BPCIA's "'shall' provision," the court observed, "cannot be read in isolation," as Congress later "specifically sets forth the consequence" for failing to disclose the application on time. App. 15a. Under that statutory remedy, "the [spon-

sor] may bring an infringement action" right away—the same remedy provided to the sponsor when the applicant fails to provide a notice of commercial marketing. *Ibid.* Because "the BPCIA explicitly contemplates that a subsection (k) applicant might fail" to provide its application in a timely manner, and "specifically sets forth the consequence for such failure," it follows that "'shall' * * * does not mean 'must.'" *Ibid.* Otherwise, "mandating compliance [with the 'shall' provision] in all circumstances would render [the consequence provisions] superfluous, and statutes are to be interpreted if possible to avoid rendering any provision superfluous." App. 17a.

Second, the court "conclude[d] that, under paragraph (*l*)(8)(A), a subsection (k) applicant may only give effective notice of commercial marketing after the FDA has licensed its product." App. 20a. As a result, Sandoz's notice provided before FDA licensure was deemed ineffective.

Third, a majority found the notice mandatory as to Sandoz and entered a 180-day injunction. The court found that "[p]aragraph (*l*)(8)(A) is a standalone notice provision in subsection (*l*)"—that is, "nothing in subsection (*l*) excuses [Sandoz] from its obligation to give notice of commercial marketing to [Amgen] after [Sandoz] has chosen not to comply with paragraph (*l*)(2)(A)." App. 25a. The court acknowledged the statutory remedy for noncompliance with the notice provision in paragraph (*l*)(9)(B), but found that it "does not apply" because "Sandoz did not comply with paragraph (*l*)(2)(A) to begin with." *Ibid.*

In entering the injunction, the court did not directly address whether Amgen showed irreparable

harm to support injunctive relief. Instead, it merely referred to its earlier order that summarily granted an injunction pending appeal: "In light of what we have decided concerning the proper interpretation of the contested provisions of the BPCIA, we accordingly order that the injunction pending appeal be extended through September 2, 2015." App. 19a.

Judge Chen dissented from the injunction order. He explained that allowing the sponsor to bring an immediate declaratory judgment lawsuit for infringement—the remedy in paragraph 9 for either failing to provide the application, or failing to provide the marketing notice—eliminated any need for injunctive relief. That is, once the sponsor may bring "an unrestricted patent infringement action," the bar on filing suit disappears, and the notice serves no purpose. App. 51a.

As Judge Chen further explained, "[t]he practical consequence of the majority's interpretation is that (*l*)(8)(A) provides an inherent right to an automatic 180-day injunction. The majority provides no basis in the statutory language to support this automatic injunction." App. 52a. He continued: "If Congress intended to create a 180-day automatic stay it understood how to do so. It could have tied FDA approval to the notice provision. Yet, Congress declined to link FDA approval to a single provision in subsection (*l*). At bottom, the majority's view is in tension with the defined purpose of (*l*)(8) while providing the [sponsor] with an atextual 180-day exclusivity windfall." App. 52a–53a.

Judge Chen's windfall prediction proved correct. As expected, Amgen never sought a preliminary in-

junction during the 180-day period. Instead, it enjoyed its judicial reprieve from competition, which had nothing to do with patent rights. In the meantime, cancer patients had to wait an additional six months after FDA approval for their lower-priced drug provided by competition.

REASONS FOR GRANTING THE WRIT

I. Review is needed to prevent pointless, 180-day injunctions untethered to patent rights or regulatory exclusivity.

It is undisputed that Amgen never sought an injunction to protect any patent rights during the 180-day injunction period here. Yet Amgen convinced the majority below to block cancer patients from receiving a lower-priced (and potentially life-saving) product for this entire period *solely* on the ground that the BPCIA forbade such marketing. The majority offered no congressional rationale for this result, much less an explanation for why Congress would have created such a six-month exclusivity period via the convoluted method of a mandatory notice triggered by FDA approval, followed by an implied right to an automatic injunction. That notion is foreclosed by the Act's text and structure, as well as this Court's precedents. Moreover, the ruling has implications for every case arising under the BPCIA, warranting immediate review.

A. The panel never explained why Congress would have bestowed six months of windfall exclusivity.

1. By its terms, the BPCIA's notice requirement does not create an automatic injunction regardless of patent rights; it describes when the sponsor may

"*seek* a preliminary injunction * * * *with respect to any patent*." 42 U.S.C. § 262(*l*)(8)(B) (emphasis added). Thus, if the sponsor has no "injunction" to "seek" on "any patent," it certainly lacks any basis for receiving an automatic, 180-day injunction.

After all, the subsection is entitled "Patents," and the notice provision is entitled "Notice of commercial marketing and preliminary injunction." Given this plain language, Congress surely did not intend to award an injunction divorced from "[p]atents."

Confirming this conclusion, the statute provides that no "action * * * for a declaration *of infringement* * * * *of any patent*" may occur "prior to the date notice is received." *Id.* § 262(*l*)(9)(B) (emphasis added). Conversely, if the applicant "fails to complete" the "action required under * * * paragraph (8)(A)"—i.e., if it fails to send the notice of commercial marketing—the "sponsor * * * may bring an action * * * for a declaration *of infringement* * * * *of any patent*." *Id.* § 262(*l*)(9)(B) (emphasis added). In both cases, the BPCIA provides for an injunction only if tied to a showing of patent infringement.

Indeed, this is the only rationale the majority gave for requiring the marketing notice "after FDA licensure"—namely, to "allow[] the [sponsor] to effectively determine whether, and on which patents, to seek a preliminary injunction." App. 21a. Amgen said the same thing below, "explain[ing] that giving notice after FDA licensure provides time for the [sponsor] * * * to resolve patent disputes." App. 19a. As the majority summed things up, "[t]he purpose of paragraph (*l*)(8)(A) [is] clear: requiring notice of commercial marketing * * * to allow the [sponsor] a period of

time to assess and act upon its patent rights." App. 25a-26a.

In short, everybody agrees that the marketing notice exists to trigger injunction litigation resolving any remaining patent rights. Where, as here, the sponsor presses no patents that could support such an injunction, no injunction is authorized. Review is needed to make that clear, and to prevent windfall injunctions like the one entered below—injunctions that will cost taxpayers billions of dollars.

2. Precisely because the BPCIA ties the marketing notice to "patent rights," it also makes no sense to tie the notice to FDA approval—which has nothing to do with patent rights. Subsection (*l*) is entitled "Patents" and concerns patent litigation, not regulatory exclusivity. Nor is the FDA approval process contingent on the marketing notice. Thus, there is no purpose in delaying this notice, which merely triggers any phase-two litigation, until FDA approval. As the petition shows, a host of textual indicators confirm this conclusion. Pet. 23-27. But consider, in particular, paragraph (*l*)(7).

This paragraph, entitled "Newly issued or licensed patents," explains what to do when a patent "is issued to * * * the [sponsor] after * * * the [sponsor] provided the list to the * * * applicant[.]" 42 U.S.C. § 262(*l*)(7)(A). In that case, where the "sponsor reasonably believes that * * * a claim of patent infringement could be reasonably asserted[,]" the sponsor "shall * * * provide to the [applicant] a supplement to the list * * * *and such patent shall be subject to paragraph (8).*" *Id.* § 262(*l*)(7)(B) (emphasis added). Paragraph 8 is the marketing notice requirement. Thus, under paragraph (*l*)(7), a newly issued patent cannot

be litigated right away; it must await the marketing notice—which, under the decision below, must await FDA approval. Thus, under the majority's reasoning, the parties must wait to litigate newly issued or licensed patents until after FDA approval.

This interpretation makes no sense. Suppose the parties begin phase-one patent litigation in year 5 of the 12-year marketing exclusivity and conclude that litigation in year 8. But then in year 9, while the parties await FDA approval, a new patent may issue. Under the decision below, the parties must sit on their hands for 3 years waiting for FDA approval before they can even *begin* to litigate the new patent.

Why? Because, again, under paragraph (*l*)(7), "such patent shall be subject to paragraph (8)" (*ibid.*)—that is, the notice requirement. And that notice, according to the opinion below, cannot validly be sent until FDA approval. The majority's reading thus delays litigation for no apparent purpose.

Indeed, the majority itself acknowledged this result: "Subsection 262(*l*) also provides that the applicant give notice of commercial marketing to the [sponsor] at least 180 days prior to commercial marketing of its product licensed under subsection (k), which then allows the [sponsor] a period of time to seek a preliminary injunction *based on * * * any newly issued or licensed patents*. App. 7a (emphasis added). Why would Congress require the parties to wait until FDA approval to begin litigating new patents? The majority never directly addresses this question. Under a proper reading of the statute, notice may be given even if FDA approval is years away.

3. The majority posits that "[r]equiring that a product be licensed before notice of commercial mar-

keting ensures the existence of a fully crystallized controversy regarding the need for injunctive relief." App. 21a. But this rationale does not make sense.

First, the statute itself contemplates that the vast majority of patents (i.e., those litigated in phase one) will be fully addressed years before FDA approval. *Ibid.* The Act authorizes patent litigation seeking permanent injunctions to begin after year four of the 12-year exclusivity. Thus, Congress obviously contemplated that this litigation would be completely resolved by the end of year 12. 42 U.S.C. §§ 262(k)(7) & (*l*)(6), (9). Subject to the limitations of Article III, and as with litigation under the Hatch-Waxman Act, Congress considered these disputes to be "fully crystallized" before FDA approval.[2]

Second, the majority misconstrues the purpose of the notice, which, as discussed, addresses only phase-two patents—to the extent any exist. Phase-two patent disputes are no less capable of being "fully crystallized" before FDA approval than phase-one disputes. A patent is relegated to phase-two status because the parties decided to postpone that particular dispute, not because the dispute was not ripe. *Supra* at 4-8. Thus, delaying the notice of commercial marketing until FDA approval accomplishes nothing—other than to provide sponsors with windfall protection from competition. *Supra* at 11-13.

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[2] Moreover, courts have routinely entertained preliminary injunction motions even though the generic drug manufacturer was merely seeking FDA approval. See, *e.g.*, *Glaxo Group Ltd.* v. *Ranbaxy Pharms, Inc.*, 262 F.3d 1333, 1338 (Fed. Cir. 2001); *The Research Found.* v. *Mylan Pharm. Inc.*, 723 F. Supp. 2d 638, 644 (D. Del. 2010).

4. Third, the majority's reading is in tension with the language of § 262(*l*)(8)(A) directing that notice be provided "not later than 180 days before the date of the first commercial marketing." The phrase "not later than" confirms that Congress wished to encourage early notice while giving applicants flexibility on timing. But for applicants that have already succeeded in preparing their products for market by FDA approval—an endeavor that may take a decade and hundreds of millions of dollars—the majority below effectively read the statute to provide that notice be provided "not *sooner* than 180 days before" commercial marketing.

This turns the Act's incentive structure on its head. The majority took language designed to expedite biosimilar competition and rewrote it to delay competition—to the detriment of consumers needing lower-cost medicines. Review is warranted.

B. Congress created no private right to enforce the notice requirement, and an automatic injunction would violate *eBay*.

1. Compounding its error, the majority inexplicably sidestepped Sandoz's argument that Congress never created a private right to seek injunctive relief to enforce the 180-day notice. See C.A. No. 15-1499, *Amgen Inc.* v. *Sandoz Inc.*, Dkt. 69 at 49-54. As this Court has repeatedly emphasized, "courts should not create liability * * * where Congress has elected not to." *E.g.*, *Limelight Networks, Inc.* v. *Akamai Techs., Inc.*, 134 S. Ct. 2111, 2118 (2014). "When Congress intends private litigants to have a cause of action to support their statutory rights, the far better course is for it to specify as much when it creates those rights." *Cannon* v. *Univ. of Chicago*, 441 U.S. 677, 717 (1979)

(emphasis added). As Congress here created no claim for the injunction entered below, it should be vacated.

Although the BPCIA confers a private right to seek declaratory relief as to patent rights if the applicant refuses either to participate in the patent exchange or to provide the 180-day notice (42 U.S.C. §§ 262(*l*)(9)(B), (C)), the Act does not confer a private right to enforce the notice provision. There certainly is no express right, as Amgen conceded in not alleging a private right of action under the BPCIA but, instead, seeking to enforce California law. App. 9a; Oral Arg. Tr. 16:3-6, *Amgen, Inc.* v. *Sandoz, Inc.*, No. 3:14-cv-04741 (N.D. Cal. Mar. 13, 2015).

Further, the standard for implying a private right of action is strict: Courts must ask whether the statute "displays an intent to create not just a private right but also a private remedy." *Alexander* v. *Sandoval*, 532 U.S. 275, 286 (2001). Absent such intent, "a cause of action does not exist and courts may not create one, no matter how desirable that might be as a policy matter, or how compatible with the statute." *Id.* at 286-287.

There is no evidence that Congress intended to create a private right of action to enforce paragraph (*l*)(8)(A). Indeed, the BPCIA provides the remedy for failing to provide the 180-day notice—an immediate declaratory judgment action (the same remedy the majority below found barred an injunction to compel compliance with paragraph (*l*)(2)). 42 U.S.C § 262(*l*)(9)(B); App. 12a-18a. And "[t]he express provision of one method of enforcing a substantive rule suggests that Congress intended to preclude others." *Sandoval*, 532 U.S. at 290. It is "elemental" that where a statute provides a remedy, courts must be

"especially reluctant to provide additional remedies." *Karahalios* v. *Nat'l Federation of Federal Empl., Local 1263*, 489 U.S. 527, 533 (1989).

Had Congress intended to create a different private right of action authorizing an automatic 180-day injunction here, it could have said a court "shall order an injunction," or at least "consider immediate injunctive relief." But while Congress used this precise language elsewhere in the BPCIA, it used no such language in paragraph (*l*)(8).

Specifically, when adopting the BPCIA, Congress provided that, "[f]or an act of infringement, * * * [*t*]*he court shall order a permanent injunction* prohibiting any infringement of the patent by the biological product" under circumstances not relevant here. 35 U.S.C. § 271(e)(4) (emphasis added). Elsewhere, Congress provided that the unauthorized disclosure of confidential information "shall be deemed to cause [the applicant] to suffer irreparable harm," and thus "the court *shall consider immediate injunctive relief.*" 42 U.S.C. § 262(*l*)(1)(H) (emphasis added). In short, Congress knew how to address injunctive relief in the BPCIA when it wanted to—whether by commanding that "the court shall order" or "shall consider" an injunction. Here it did neither. And "[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally." *Russello* v. *United States*, 464 U.S. 16, 23 (1983) (quotation omitted).

Similarly, Congress created a private counterclaim in the Hatch-Waxman Act, which contains "certain similarities in its goals and procedures" to the BPCIA. App. 5a. Specifically, 21 U.S.C.

§ 355(j)(5)(C)(ii)(I) authorizes "a counterclaim seeking an order requiring the [brand] to correct or delete [certain] patent information" submitted to the FDA. See generally *Caraco Pharm. Labs., Ltd.* v. *Novo Nordisk A/S*, 132 S. Ct. 1670 (2012). Thus, Congress knows how to create a private right of action and remedy in this arena, yet it chose not to do so to enforce the 180-day notice provision.

Instead, subsection (*l*) of the BPCIA creates a streamlined process to allow biosimilar applicants and sponsors to determine which patents should be litigated, and when. Congress also created a remedy for any failure to act under subsection (*l*)—namely, the right to sue immediately. Viewing the BPCIA framework as a whole, it is plain that Congress created no private right of action to enforce compliance with paragraph (*l*)(8)(A), much less to obtain an automatic 180-day injunction. Insofar as a private right of action is needed to enforce the patent disclosures and exchange provisions of the BPCIA, it is the responsibility of Congress, not the courts, to create one. *E.g.*, *3M* v. *Barr Labs., Inc.*, 289 F.3d 775, 777 (Fed. Cir. 2002); *Mylan Pharms, Inc.* v. *Thompson*, 268 F.3d 1323, 1332 (Fed. Cir. 2001).

Ultimately, Amgen's claim for a 180-day injunction fails because paragraph (8)(A) contains no "rights-creating language" entitling it to bring a private right of action to enforce the 180-day notice provision, as opposed to its patent rights. See *Alexander*, 532 U.S. at 288 (quotation omitted); *Touche Ross & Co.* v. *Redington*, 442 U.S. 560, 571–576 (1979) ("[I]mplying a private right of action on the basis of congressional silence is a hazardous enterprise, at best."). Far from it: Subsection 262(*l*) of the BPCIA,

entitled "Patents," merely provides a framework to help the parties address patent disputes efficiently.

2. In any event, even if Congress implied a private right of action to enforce the BPCIA's notice provision, it still would be inappropriate to enter what is, in effect, an *automatic* 180-day injunction as a remedy for failure to provide the notice. This is particularly true where, as here and in *amici*'s case, the notice serves no statutory purpose.

Nothing in the BPCIA alters the longstanding rule that "whether to grant or deny injunctive relief rests within the equitable discretion of the district courts," or that "such discretion must be exercised consistent with traditional principles of equity." *eBay Inc.*, 547 U.S. at 394. Moreover, this Court "has consistently rejected invitations to replace traditional equitable considerations with a rule that an injunction automatically follows" a statutory violation. *Id.* at 392–393. How could the sponsor be irreparably harmed absent the 180-day injunction if the sponsor has no intent to seek an injunction based on patent rights? The majority avoided that question entirely.

Certiorari should be granted to confirm that there is no private right of action to enforce the notice provision or, alternatively, that an injunction may issue only if necessary to protect patent rights and only if the patentee first satisfies *eBay*.

II. Review is needed to close the three-way split in the decision below and set the competitive framework for the biosimilars industry.

How to read the BPCIA's marketing notice provision is an important question under Rule 10, and the Court should not allow the issue to "percolate" merely

because the question is one of "first impression." Pet. 3a. The panel split on the key question regarding injunctive relief, and the Federal Circuit declined to grant en banc review—even though all three judges called the question a "riddle" and an "enigma" (App. 4a, 54a), and even though the majority's decision threatens to undermine the competition that Congress expected to "save government and private payors tens of billions of dollars." Pet. 3. Resolving this question is vital to the functioning of the growing, multibillion-dollar biosimilars industry. The provision at issue is a key element of a significant statute governing an industry at the vanguard of health care delivery in the 21st Century. And the Federal Circuit's decision is already being misused in lower courts to stymie Congress's goal of promoting biosimilar competition. Pet. 41.

For example, in its dispute with *amici*, Janssen argues that notice of commercial marketing requires an automatic 180-day injunction even though, unlike here, Celltrion timely provided its aBLA. Janssen thus seeks to expand the ruling below to authorize an automatic 180-day injunction following FDA approval for *all* sponsors. This issue affects the whole industry, warranting review of the notice provision.

These and other "pending cases" (Pet. 41) underscore the need for this Court's review. "Because the Federal Circuit has exclusive jurisdiction over appeals from all United States District Courts in patent litigation, the rule that it applied in this case * * * is a matter of special importance to the entire Nation." *Cardinal Chem. Co.* v. *Morton Int'l, Inc.*, 508 U.S. 83, 89 (1993). Review is all the more appropriate in light of the splintered decision below. See, *e.g.*, *United States* v. *Tohono O'Odham Nation*, 563 U.S. 307, 310

(2011) (granting review of a decision by a "divided panel of the * * * Federal Circuit"); *Microsoft Corp.* v. *AT & T Corp.*, 550 U.S. 437, 447 (2007) (same); *Merck KGaA* v. *Integra Lifesciences I, Ltd.*, 545 U.S. 193, 201 (2005) (same).

This Court has not hesitated to take up similar questions under the Hatch-Waxman Act, where those questions were critical to the incentives and competitive frameworks created by Congress. In *Eli Lilly & Co.* v. *Medtronic, Inc.*, 872 F.2d 402, 404 (Fed. Cir. 1989), *aff'd*, 496 U.S. 661 (1990), the Federal Circuit decided a "question of first impression, namely, whether the noninfringement defense of 35 U.S.C. § 271(e)(1) * * * applies to medical devices." But that did not deter this Court from granting certiorari, presumably because a circuit-split was impossible, and a definitive ruling was needed.

Similarly, *Caraco Pharm. Labs.* v. *Novo Nordisk*, 601 F.3d 1359 (Fed. Cir. 2011)—which likewise produced three opinions below—was the Federal Circuit's first occasion to address whether the Hatch-Waxman Act's counterclaim provision authorized generics to contest the accuracy of patent information that brands submit to FDA. Again, this Court did not delay in taking up the matter, presumably because the counterclaim was vital to "facilitat[ing] the approval of generic drugs as soon as patents allow." 132 S. Ct. at 1676. Here, the issue is also vital to facilitate new drugs and foster competition.

Even outside the intellectual property context, this Court has often reviewed important statutory questions of first impression. Thus, in *United States* v. *Donovan*, this Court "granted certiorari to resolve * * * issues [that] concern the construction of a major

federal statute." 429 U.S. 413, 422 (1977); see also *Am. Fed. of Musicians* v. *Wittstein*, 379 U.S. 171, 175 (1964) ("grant[ing] certiorari" where the question presented was "an important one of first impression under the [statute]").

Likewise, this Court reviews cases that "raise[] questions of importance in the administration of the [statute]." *United States* v. *Ruzicka*, 329 U.S. 287, 288 (1946); see also *Nat'l Broiler Mktg. Ass'n* v. *United States*, 436 U.S. 816, 820 (1978) ("Because of the importance of the issue for the [business] community and for the administration of the [statute], we granted certiorari."); *Rothensies* v. *Elec. Storage Battery Co.*, 329 U.S. 296, 299 (1946) ("The gravity of this holding to the administration of the [statute] led us to grant certiorari.").

All of these reasons call for review here, especially as Congress plainly sought to enable brand and generic drug makers to resolve their disputes quickly—thus expediting competition that benefits patients. Review is needed now.

CONCLUSION

For the foregoing reasons, certiorari should be granted.

Respectfully submitted.

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